



August 3, 2004

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-15

Animal and Plant
Health Inspection
Service

Subject: Name Change for Biologicals Containing Avian Influenza Virus

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

Center for Veterinary
Biologics

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I. PURPOSE

This notice serves to inform licensees, permittees, and applicants of a change in the true name of products containing avian influenza virus.

II. BACKGROUND

For Avian Influenza Vaccines, it has been the policy of APHIS to only include the hemagglutinin (H) subtype in the true name of the product. For example, the true name of a product containing the H1 subtype is Avian Influenza Vaccine, H1 Subtype, Killed Virus. With the recent employment of DIVA (differentiating infected from vaccinated animals) strategies in avian influenza virus eradication efforts, it is also important to know the neuraminidase (N) subtype. Knowing the N subtypes can allow for the differentiation between infection with field strains and immune responses strictly due to vaccine strains of avian influenza virus.

III. ACTION

All licenses issued subsequent to September 30, 2004, for products containing an avian influenza virus fraction shall include both the H subtype and N subtype in the true name. For currently licensed products, Outlines of Production and labeling should be revised not later than March 31, 2005. Existing inventory of approved labels may be used until September 30, 2006.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics